§ 522.970 Flunixin.

(a) *Specifications.* Each milliliter of solution contains flunixin meglumine equivalent to 50 milligrams (mg) flunixin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) See Nos. 000061, 055529, and 061623 for use as in paragraph (e) of this section.

(2) See No. 000856 for use as in paragraph (e)(1) of this section.

(3) See Nos. 057561 and 059130 for use as in paragraphs (e)(1) and (2) of this section.

(c) *Related tolerances.* See § 556.286 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* 0.5 mg per pound (/lb) of body weight per day, intravenously or intramuscularly, for up to 5 days.

(ii) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders, and alleviation of visceral pain associated with colic.

(iii) *Limitations.* Do not use in horses intended for human consumption.

(2) *Cattle*—(i) *Amounts and indications for use*—(A) Administer 1.1 to 2.2 mg/kilogram (kg) (0.5 to 1.0 mg/lb) of body weight per day intravenously, as a single dose or divided into two doses administered at 12-hour intervals, for up to 3 days for control of pyrexia associated with bovine respiratory disease and endotoxemia or for control of inflammation in endotoxemia.

(B) Administer 2.2 mg/kg (1.0 mg/lb) of body weight once intravenously for control of pyrexia associated with acute bovine mastitis.

(ii) *Limitations.* Cattle must not be slaughtered for human consumption within 4 days of last treatment. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. Do not use in dry dairy cows. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal.

(B) For control of pyrexia associated with acute bovine mastitis.

(iii) *Limitations.* Do not slaughter for food use within 4 days of last treatment. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. For Nos. 000061, 055529, 059130, and 061623: Do not use in dry dairy cows. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. For No. 057561: Not for use in lactating or dry dairy cows.

(3) *Swine*—(i) *Amount.* Administer 2.2 mg/kg (1.0 mg/lb) of body weight as a single intramuscular injection.

(ii) *Indications for use.* For the control of pyrexia associated with swine respiratory disease.

(iii) *Limitations.* Swine must not be slaughtered for human consumption within 12 days of last treatment.

[42 FR 39103, Aug. 2, 1977, as amended at 52 FR 7832, Mar. 13, 1987; 60 FR 54942, Oct. 27, 1995; 62 FR 22888, Apr. 28, 1997; 63 FR 38749, July 20, 1998; 67 FR 9400, Mar. 1, 2002; 68 FR 70701, Dec. 19, 2003; 69 FR 53618, Sept. 2, 2004; 69 FR 60308, Oct. 8, 2004; 70 FR 48868, Aug. 22, 2005; 70 FR 70998, Nov. 25, 2005; 71 FR 15564, Mar. 29, 2006; 71 FR 16222, Mar. 31, 2006; 73 FR 2809, Jan. 16, 2008; 73 FR 28037, May 15, 2008; 74 FR 6994, Feb. 12, 2009; 74 FR 34236, July 15, 2009; 75 FR 13225, Mar. 19, 2010; 75 FR 76260, Dec. 8, 2010]

§ 522.995 Fluprostenol sodium injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains fluprostenol sodium equivalent to 50 micrograms of fluprostenol.

(b) *Sponsor.* See 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 0.55 microgram fluprostenol per kilogram of body weight.

(2) *Indications for use.* The drug is used in mares for its luteolytic effect to control the timing of estrus in estrous cycling and in clinically anestrous mares that have a corpus luteum.

(3) *Limitations.* Administer by intramuscular injection only. *Warning:* Not for use in horses intended for food. For veterinary use only. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Women of childbearing age, asthmatics, and persons with bronchial

and other respiratory problems should exercise extreme caution when handling this product. In the early stages, women may be unaware of their pregnancies. Fluprostenol is readily absorbed through the skin and can cause abortion and/or bronchiospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

[44 FR 52191, Sept. 7, 1979, as amended at 47 FR 22092, May 21, 1982]

§ 522.1002 Follicle stimulating hormone.

(a)(1) *Specifications*. Each package contains 2 vials. One vial contains dry, powdered, porcine pituitary gland equivalent to 75 units (NIH-FSH-S1) of follicle stimulating hormone. The other vial contains 10 milliliters of aqueous diluent.

(2) *Sponsor*. See No. 052923 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) *Dosage*. 12.5 units of follicle stimulating hormone twice a day for 3 days (a total of 75 units). To effect regression of the corpus luteum, prostaglandin should be given with the 5th dose.

(ii) *Indications for use*. For induction of superovulation in cows for procedures requiring the production of multiple ova at a single estrus.

(iii) *Limitations*. For intramuscular use in cows that are not pregnant and have a normal corpus luteum. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications*. The drug is a lyophilized pituitary extract material. Each 10-milliliter vial contains an amount equivalent to 50 milligrams of standard porcine follicle stimulating hormone and is reconstituted for use by addition of 10 milliliters of 0.9 percent aqueous sodium chloride solution.

(2) *Sponsor*. See 063112 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) *Dosage*. Cattle and horses, 10–50 milligrams; sheep and swine, 5–25 milligrams; dogs, 5–15 milligrams.

(ii) *Indications for use*. The drug is used as a supplemental source of follicle stimulating hormone where there is a general deficiency in cattle, horses, sheep, swine, and dogs.

(iii) *Limitations*. Administer intramuscularly, subcutaneously, or intravenously. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 47377, Sept. 9, 1993, as amended at 62 FR 62242, Nov. 21, 1997; 76 FR 2808, Jan. 18, 2011]

§ 522.1004 Fomepizole.

(a) *Specifications*. Each vial contains 1.5 grams fomepizole (1.5 milliliter (mL) of 1.0 gram per mL solution).

(b) *Sponsors*. See Nos. 046129 and 063286 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. 20 milligrams per kilogram (mg/kg) of body weight intravenously initially, followed by 15 mg/kg at 12 and 24 hours, and 5 mg/kg at 36 hours.

(2) *Indications for use*. As an antidote for ethylene glycol (antifreeze) poisoning in dogs who have ingested or are suspected of having ingested ethylene glycol.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 68147, Dec. 27, 1996, as amended at 71 FR 28266, May 16, 2006; 74 FR 26952, June 5, 2009; 74 FR 47725, Sept. 17, 2009; 77 FR 26697, May 7, 2012]

§ 522.1010 Furosemide.

(a) *Specifications*—(1) Each milliliter (mL) of solution contains 50 milligrams (mg) furosemide monoethanolamine.

(2) Each mL of solution contains 50 mg furosemide diethanolamine.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use of products described in paragraph (a) of this section for use as in paragraph (d) of this section.

(1) No. 000010 as described in paragraph (a)(1) of this section for use as in paragraphs (d)(1) and (d)(2)(ii) of this section.

(2) No. 061623 as described in paragraph (a)(2) of this section for use as in paragraph (d)(2)(ii) of this section.

(3) No. 000859 as described in paragraph (a)(2) for use as in paragraphs (d)(1), (d)(2)(i), and (d)(3) of this section.

(4) No. 000061 as described in paragraph (a)(2) for use as in paragraphs (d)(1), (d)(2)(iii), and (d)(3) of this section.